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EXAMINER

LEWIS, AARON J

ART UNIT

PAPER NUMBER

3743

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/636,055

Applicant(s)

AYLSWORTH ET AL.

Examiner

AARON J. LEWIS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 11-20, 22-34, 37 and 38 is/are rejected.
- 7) ☒ Claim(s) 6-10, 21, 35 and 36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-5, 11-14, 23-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richey, II et al. ('165) in view of Frye et al. ('088).

The difference between Richey, II et al. and claim 1 is a conserver coupled to the regulated therapeutic gas stream, the conserver operable to deliver a bolus of therapeutic gas during inhalation of a patient.

Frye et al. teach a conserver (42) coupled to the regulated therapeutic gas stream, the conserver operable to deliver a bolus of therapeutic gas during inhalation of a patient for the purpose of providing oxygen to a patient upon sensing an inhalation attempt and shutting off oxygen to a patient upon sensing an exhalation attempt (col.5, lines 9-12) thereby preventing wasting of oxygen gas.

It would have been obvious to modify Richey, II et al. to include a conserver coupled to the therapeutic gas stream because it would have provided a means for providing oxygen to a patient upon sensing an inhalation attempt and shutting off oxygen to a patient upon sensing an exhalation attempt thereby preventing wasting of oxygen gas as taught by Frye et al..

As to claim 2, Richey, II et al. disclose a gas sense device (360 and col.7, lines 38-46) fluidly coupled to the cylinder connector (350), the gas sense device operable to detect purity of the therapeutic gas; and wherein the trans-fill system is operable to allow a portion of the gas within a connected portable cylinder (500) to flow to the gas sense device, and wherein the trans-fill system refrains from filling the connected portable cylinder if the purity of the gas in the bottle, as determined by the gas sense device, falls below a predetermined threshold (col.7, line 40).

As to claims 3-5, while Richey, II et al. do disclose sensor (360) to be oxygen specific there is no express disclosure of the particular type of oxygen sensor (360), it is submitted that it would have been obvious to employ any well known type of oxygen sensor including one which detects oxygen by density as an obvious matter of design choice with no new or unobvious results accruing. Inasmuch as no criticality is seen in an oxygen density sensor, it is submitted that the oxygen sensor of Richey, II et al. would function as well as an oxygen sensor that detects by density.

As to claim 11, cylinder (30) of Richey, II et al. is coupled to the compressed therapeutic gas stream fully capable of providing therapeutic gas from the cylinder when the intensifier is not in operation (col.8, lines 7-16).

As to claims 12-14, inasmuch as cylinder (30) of Richey, II et al. is a tank, it constitutes a portable component; moreover, it would have been obvious to designate it either internal or external relative to the overall trans-fill system. The mere use of each of the terms internal and external does not convey a structural distinction as they relate

to the relative physical cooperative relationship between cylinder (30) and the overall trans-fill system.

Claim 23 is substantially equivalent in scope to claim 11 and is included in Richey, II et al. as modified by Frye et al. for the reasons set forth above with respect to claim 11.

As to claim 24, Richey, II et al. disclose an oxygen concentrator (10,12) coupled to the compressor (100), the oxygen concentrator operable to provide therapeutic gas to the compressor.

As to claim 25, while Richey, II et al. are not specific as to the particular type of oxygen concentrator, it would have been obvious to substitute any well known type of oxygen concentrator including a pressure swing absorption system as one well known oxygen concentrator for another as an obvious matter of design choice. Inasmuch as no criticality is seen for a pressure swing absorption system, it is submitted that the oxygen concentrator of Richey, II et al. would have functioned as efficiently as a pressure swing absorption system.

As to claim 26, Richey, II et al. disclose a connector (210,300) operable to selectively couple the cylinder to the system.

As to claims 27,28, inasmuch as cylinder (30) of Richey, II et al. is a tank, it constitutes a portable component; moreover, it would have been obvious to designate it either internal or external relative to the overall trans-fill system. The mere use of each of the terms internal and external does not convey a structural distinction as they relate to the relative physical cooperative relationship between cylinder (30) and the overall trans-fill system.

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As to claim 29, cylinder (30) of Richey, II et al. is coupled to the compressed therapeutic gas stream fully capable of providing therapeutic gas from the cylinder when the intensifier is not in operation (col.8, lines 7-16).

As to claim 30, the compressor (22,100) of Richey, II et al. by definition includes an intensifier inasmuch as the compressor increases (i.e. intensifies) the pressure of an incoming stream of gas. Further, compressor (100) increases (i.e. intensifies) the pressure of oxygen gas within tank (500) relative to the pressure of the oxygen gas at the input of the compressor.

3. Claims 18,19,33,34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richey, II et al. ('165).

As to claims 18 and 19, while Richey, II et al. do disclose sensor (360) to be oxygen specific there is no express disclosure of the particular type of oxygen sensor (360), it is submitted that it would have been obvious to employ any well known type of oxygen sensor including one which detects oxygen by density as an obvious matter of design choice with no new or unobvious results accruing. Inasmuch as no criticality is seen in an oxygen density sensor, it is submitted that the oxygen sensor of Richey, II et al. would function as well as an oxygen sensor that detects by density.

As to claims 33 and 34, while Richey, II et al. do disclose sensor (360) to be oxygen specific there is no express disclosure of the particular type of oxygen sensor (360), it is submitted that it would have been obvious to employ any well known type of oxygen sensor including one which detects oxygen by density as an obvious matter of design choice with no new or unobvious results accruing. Inasmuch as no criticality is seen in

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an oxygen density sensor, it is submitted that the oxygen sensor of Richey, II et al. would function as well as an oxygen sensor that detects by density.

4. Claims 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Todd, Jr. ('630) in view of Richey, II et al. ('165) and Frye et al. ('088).

The differences between Todd, Jr. and claim 37 are an adjustable flow control device, the adjustable flow control device operable to create a continuous flow of therapeutic gas at a selected flow rate and a conserver fluidly coupled to the therapeutic gas, operable to release a bolus of therapeutic gas during a patient inhalation.

Richey, II et al. teach an adjustable flow control device (230,330), the adjustable flow control device operable to create a continuous flow of therapeutic gas at a selected flow rate (col.6, lines 61-65 and col.7, lines 33-35) for the purpose of providing the therapeutic gas to a patient at a safe and comfortable flow rate.

It would have been obvious to modify the patient conduit (20) of Todd, Jr. to include an adjustable flow control device therein because it would have provided the therapeutic gas to a patient at a safe and comfortable flow rate as taught by Richey, II et al..

Frye et al. teach a conserver (42) coupled to the regulated therapeutic gas stream, the conserver operable to deliver a bolus of therapeutic gas during inhalation of a patient for the purpose of providing oxygen to a patient upon sensing an inhalation attempt and shutting off oxygen to a patient upon sensing an exhalation attempt (col.5, lines 9-12) thereby preventing wasting of oxygen gas.

It would have been obvious to modify the patient conduit (20) Todd, Jr. to include a conserver coupled to the therapeutic gas stream because it would have provided a

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means for providing oxygen to a patient upon sensing an inhalation attempt and shutting off oxygen to a patient upon sensing an exhalation attempt thereby preventing wasting of oxygen gas as taught by Frye et al..

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 15-17,20,22,31,32 are rejected under 35 U.S.C. 102(b) as being anticipated by Richey, II et al. ('165).

As to claim 15, Richey, II et al. as discussed above with respect to claim 1 also disclose a method comprising: compressing (22,100) a stream of low-pressure therapeutic gas to form a compressed therapeutic gas stream; providing a first portion (270) of the compressed therapeutic gas steam to fill a cylinder (500); and providing a second portion (220) of the compressed therapeutic gas stream to a patient in as a bolus of therapeutic gas.

As to claim 16, Richey, II et al. disclose prior to compressing step and the providing steps, testing gas within the cylinder (col.7, lines 2-14).

As to claims 17 and 20, Richey, II et al. disclose testing the gas within the cylinder (500) by measuring the oxygen content using sensor (265,360) and refraining from filling the cylinder if the gas within the cylinder contains contaminants (col.7, lines 2-14).

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As to claim 22, Richey, II et al. disclose setting a volume of the bolus of therapeutic gas based on a sensed setting (col.6, lines 63-65) for a continuous flow of therapeutic gas through the flow meter (230,330).

As to claim 31, Richey, II et al. as discussed above with respect claim 16, also disclose an apparatus comprising; an intensifier operable to take therapeutic gas at a first pressure and increase the pressure of the therapeutic gas to a second pressure, higher than the first pressure; a fill port fluidly coupled to the therapeutic gas at the second pressure, the fill port operable to selectively couple a cylinder to be filled with therapeutic gas; a gas sense device coupled to the fill port, the gas sense device operable to detect content of gas within the cylinder prior to filling.

As to claim 32, Richey, II et al. disclose the gas sense device further comprises an oxygen-specific sensor (265,360).

Claim Objections

7. Claim 1 is objected to because of the following informalities: in line 4, "...the regulated therapeutic gas stream..." has not been previously referred to as a "regulated" therapeutic gas stream. The language of the claim should be amended to be consistent throughout. Appropriate correction is required.

Allowable Subject Matter

8. Claims 6-10,21,35,36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

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9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of the art is cited to show relevant trans-fill systems.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (703) 308-0716. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



AARON J. LEWIS
Primary Examiner
Art Unit 3743

Aaron J. Lewis
September 18, 2004